

REMARKS

Double Patenting

In the Office Action, the Examiner noted that claims 1-5, 7-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of co-pending Application No. 10/725,920.

The Examiner stated that Claims 1, 4, 5, 11, 13, 14, 22 and 23 of the instant invention appear to be identical to claims 1, 3, 4, 9, 11, 12, 20 and 21 of application '920 except for the use of "fluid" instead of "media". Although these terms do have differing scope, the term "fluid" of application '920 is fully encompassed by the term "media". Moreover, fluid would have been an obvious choice of ion conducting media because ion conducting fluid are readily available.

The Examiner also stated that Claims 2 and 12 of the instant invention appear to be substantially identical to claims 2 and 10 of application '920 except for the inclusion of polysaccharide in the instant invention. However, claims 2 and 12 of the instant invention fully encompass claims 2 and 10 of application '920.

Furthermore, the Examiner stated that Claim 3 of the instant invention fully encompasses claim 2 of application 920 because claim 2 already recited the use of polymeric materials for the wick.

In addition, the Examiner stated that Claims 4 and 13 of the instant invention fully encompass claims 3 and 11 of application '920 because the cellulose is a polysaccharide.

The Examiner also stated that the remaining dependent claims being rejected above appear to be identical to claims found in application '920.

The Examiner also stated that Claims 25-28 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 9, 20 and 21 of copending application '920 in view of Glass et al. (USP 5,306,414).

Finally, the Examiner stated that application '920 set forth all the limitations of the claims, but did not explicitly claim a coating from the set forth Markush groupings. Glass teaches in an alternate ph sensor that hydrophilic coatings of polyacrylamides facilitate the wetting of the sensor with the sample solution. The Examiner concluded that it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Glass for the claimed sensor of application '920 so as to ensure the sample sufficiently wets the sensor.

Response:

It is current USPTO policy that a timely filed terminal disclaimer in compliance with 37 CFR 1321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1130(b).

It has been established as of January 1, 1994 that a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The Applicant has amended independent claims 1, 11, 22 and 24 of the present application which Applicant believes is patentable distinguishable over Glass et al. Dependent claim 9 is dependent upon independent claim 1 and distinguishable as claim 1. Furthermore, the Attorney for the Applicant has attached a terminal disclaimer in Exhibit A to address the Examiner's comments. The Applicant believes that the terminal disclaimer overcomes the objection.

CLAIM REJECTIONS -35 USC § 112

The Examiner stated that Claims 6, 24 and 29 are rejected under 35 USC, 112 first paragraph, as failing to comply with the enablement requirement, The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

More specifically, the Examiner stated that Claim 6 specifies that the ion conduction media is a conductive polymer. Applicant never discloses this in the specification. The only materials disclosed for the ion conducting media are fluids like NaCl and KCl solutions and applicant never disclosed the use of conductive polymers. For the purpose of examination, the Examiner stated it is presumed that the applicant is referring to the polymerized (i.e. gelled) solutions based on polysaccharides, which the applicant does have support for, but clarification is requested.

The Examiner also stated that Claim 24 is similarly to claim 11 but applicant appears to have reversed which elements are in which tubes (i.e. the reference element and wick are now in the inner tubular member and the antimony sensor is in the outer tubular member. Applicant never disclosed how to do this and one possessing ordinary skill in the art

would not have been enabled to construct such a sensor based on the originally filed disclosure.

The Examiner also stated that claims 1-29 are rejected under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Specifically, the Examiner states the independent claims 1, 11, and 22-24 all refer to the reference element being in a "proximal" position. The Examiner asked "What is the element proximal with to?" The Examiner stated that it is unclear what the proximal position is referred to and clarification is requested.

Response:

It is recognized that if the claims in an application contain certain features of an invention that are not described anywhere else in the originally filed application. In this situation, the originally filed claims may constitute an adequate written description of the invention. Accordingly, if the Examiner requires the disclosure portion of the description of the invention to contain such a description, the disclosure may be amended to recite the originally filed claims to provide the necessary description of the invention, (*In re Gardner*, 480 F.2d 879, 178 USPQ 149 (C.C.P.A. 1973)).

The Examiner stated that Claim 6, 24 and 29 specifies that the ion conduction media is a conductive polymer but that the Applicant never discloses this in the specification. For the purpose of examination, the Examiner stated it is presumed that the applicant is referring to the polymerized (i.e. gelled) solutions based on polysaccharides, which the applicant does have support for, but

clarification is requested. The Examiner also stated The Examiner also stated that Claim 24 is similarly to claim 11 but applicant appears to have reversed which elements are in which tubes (i.e. the reference element and wick are now in the inner tubular member and the antimony sensor is in the outer tubular member.

The Applicant has amended the specification to provide support for claims 6, 24 and 29 in regards to the lack of support in the specification as noted by the Examiner. The Applicant believes that the amended specification overcomes the Section 35 U.S.C. 112, second paragraph objection.

The Applicant has amended independent claims 1, 22 and 23 of the present application to state that the reference element is proximal to the antimony sensor as depicted in Figure 1 of the application and as defined on page 8, lines 15-17 which state that "Located proximally from a range of 1-8 centimeters from the proximal end of the antimony sensor 24, and preferably 3-5 centimeters, is a reference element 30. Applicant asserts that claims 11 and 24, as originally drafted, defined that the reference element was proximal to the antimony sensor.

The Applicant believes that the amended independent claims (1, 6, 11 and 22-24) now overcome the 35 USC § 112 objections.

CLAIM REJECTIONS -35 USC § 103 - CHRISTNER ET AL. (5,346,606) IN VIEW
OF KLEINBERG (3,742,594

The Examiner stated that Claims 1-3, 6-9, 11, 12, 15-18, 20, 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christner et al. (USP 5,346,606) in view of Kleinberg (USP 3,742,394). The Examiner stated that Christner discloses a sensor for monitoring pH comprising an outer tubular member 24 and all inner tubular member 16 where said inner tubular member is coaxially and collinearly enclosed within the outer tubular member. (See fig. 1A.) The Examiner further stated that Christner discloses a pH sensor enclosed with the inner tubular member and a reference element 22 enclosed within the outer tubular member and located in presumably a proximal position (see 112 rejection above). Additionally, the Examiner stated that Christner further discloses a wick material 12 having one side surrounding and partially engaging the inner tubular member, and that said wick extends from the sensor to the reference element, which it is substantially engaged with. Christner further discloses an ion conducting fluid (i.e. electrolyte) retained within the wick material. The Examiner correctly noted that Christner does not explicitly disclose the use of an antimony sensor for the ion sensor.

The Examiner stated that Kleinberg discloses in an alternate sensor that antimony sensors have a number of advantages over the bulb based electrode of Christner including the ability to 'make smaller, more robust and more one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Kleinberg for the sensor of Christner so as to make the sensor smaller, more robust and more stable.

Response:

The amended independent claims 1, 11, 22 and 24 (and original independent claim 23) state that the self-condensing sensor comprises a design that promotes in certain environmental conditions, such as exposed to a patient's breath, to condense as one or more micro-droplet across the antimony sensor and the reference element. These micro-droplets complete the circuit of the present invention for measuring the pH of the micro-droplets.

Neither Christner nor Kleinberg disclose or claims a device that includes self-condensing sensor with a design that promotes in certain environmental conditions, such as exposed to a patient's breath, to condense one or more micro-droplets across said antimony sensor and said wick element which is in electrical communication with said reference element. In additional, neither Christner nor Kleinberg disclose or claim a device that cooperates with micro-droplets which function to complete the circuit of the present invention and measure the pH of the micro-droplets.

In addition, the Applicants argue respectfully that the Examiner has not met the burden of establishing a prima facie case of obviousness in accordance with current patent law.

There are several elements necessary to correctly conclude that a claim of obviousness has been established. One of the primary elements of establishing a prima facie case of obviousness is that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated

that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination."

With respect to this required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." (See *In re Geiger*, 815 F.2d 686, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987). See also *Diversitech Corp. v. Centure Steps, Inc.*, 850 F.2d 675, 678-79, 7 USPQ 2d 1315, 1318 (Fed. Cir. 1988); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 311 (Fed. Cir. 1983):

The Patent Office applies this same standard as explained by the Board, "When the incentive to combine the teachings of the references is not readily apparent, it is the duty of the examiner to explain why combination of the reference teachings is proper....Absent such reasons or incentives, the teachings of the references are not combinable. (Ex parte Skinner, 2 USPQ 2d 1788, 1790 (B.P.A.I. 1987)).

Thus, Applicants respectfully submit that the independent claims 1, 11, 22-24 of the present application are patentably distinct and are fully distinguishable over Christner et al. in view of Kleinberg. Furthermore, since claims 2 and 3 (choice of wick material) 6 (ion conduction media comprises a conductive polymer) and 7-8 (reference element material) and 9 (coaxial offset configuration), are dependent upon independent claim 1, these dependent claims are patentably distinct and fully distinguishable over Christner et al. in view of Kleinberg as is claim 1. In addition, since claims 12 (choice of wick material),

15-16, (reference element material), 17 (coaxial offset configuration), and 18 and 20 (electrical communications) are dependent upon independent claim 11, these dependent claims are patentably distinct and fully distinguishable over Christner et al. in view of Kleinberg as is claim 11. Withdrawal of this 103(a) rejection is therefore requested.

CLAIM REJECTIONS -35 USC § 103 - CHRISTNER ET AL. (5,346,606) IN
VIEW OF KLEINBERG (3,742,594 AND IN FURTHER VIEW OF LEONARD

The Examiner stated that Claims 3, 4, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christner and Kleinberg as set forth for claims 1 and 9 above, and in further view of Leonard. The Examiner stated that Christner and Kleinberg set forth all the limitations of these claims, but did not explicitly set forth a cellulose based material or a water based gel for the ion conducting fluid. Leonard teaches in an alternate reference electrode that the addition of cellulose based materials to the ion conducting fluid gels the electrolyte thereby preventing loss of ion conducting fluid from the reference electrode. See col. 5, 11. 14-23. The Examiner stated that it would have been obvious to one of ordinary skill in the art at the time the invention was being 'made to utilize the teaching of Leonard for the sensor of Christner and Kleinberg so as to prevent ion conducting fluid loss from the sensor.

Response:

The dependent claims 3, 4, 13 and 14 are dependent upon the amended independent claims 1 and 11 of the present application. The amended independent claims 1 and 11 disclose and claim a self-condensing sensor with a design that promotes in certain environmental conditions, such as when exposed to a patient's breath, to condense as one or more micro-droplets across said antimony sensor and said reference element (via said wick element). In addition, the Applicants' device is designed to cooperate with micro-droplets obtained from a certain environmental situation, such as exposure patient's breath which functions to complete the circuit of the present invention and measure the pH of the micro-droplets.

Neither Christner, Kleinberg nor Leonard disclose or claim a device that includes self-condensing sensor with a design that promotes in certain environment conditions, such as exposure to a patient's breath, to condense as one or more micro-droplets across said antimony sensor and said wick element which is in electrical communication with said reference element. In addition, neither Christner, Kleinberg nor Leonard disclose or claim a device that cooperates with micro-droplets obtained e.g. from a patient's breath, that function to complete the circuit of the present invention for measuring the pH of the micro-droplets.

In addition, the Applicants argue respectfully that the Examiner has not met the burden of establishing a prima facie case of obviousness in accordance with current patent law.

There are several elements necessary to correctly conclude that a claim of obviousness has been established. One of the primary elements of establishing a prima facie case of obviousness

it that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination."

With respect to this required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." (See *In re Geiger*, 815 F.2d 686, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987). See also *Diversitech Corp. v. Centure Steps, Inc.*, 850 F.2d 675, 678-79, 7 USPQ 2d 1315, 1318 (Fed. Cir. 1988); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 311 (Fed. Cir. 1983):

The Patent Office applies this same standard as explained by the Board, "When the incentive to combine the teachings of the references is not readily apparent, it is the duty of the examiner to explain why combination of the reference teachings is proper....Absent such reasons or incentives, the teachings of the references are not combinable. (Ex parte Skinner, 2 USPQ 2d 1788, 1790 (B.P.A.I. 1987)).

Thus, Applicants respectfully submit that claims 3, 4, 13 and 14 that are dependent on independent claims 1 and 11 of the present application are patentably distinct and are fully distinguishable over Christner et al. in view of Kleinberg and in further view of Leonard as are independent claims 1 and 11. Withdrawal of this 103(a) rejection is therefore requested.

CLAIM REJECTIONS -35 USC § 103 - CHRISTNER ET AL. (5,346,606) IN VIEW
OF KLEINBERG (3,742,594 AND IN FURTHER VIEW OF MOSLEY ET AL.
(6,653,842)

The Examiner stated that Claims 10, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Christner and Kleinberg as applied to claims 1 and 11 above, and further in view of Mosley et al (6,653,842). With respect to claims 10 and 19, the Examiner stated that the references set forth all the limitations of the claim, but did not explicitly disclose the presence of a display which processes information from the sensor. Mosley discloses in an alternate pH sensor that the data should be subsequently processed and displayed for use of the measured data. See col. 10. II. 1-9 and col. 11, II. 5-17. The Examiner stated that it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Mosley for the sensor of Christner and Kleinberg so that the collected data can be converted into an appropriate readable pH number useable by the operator of the sensor. Furthermore, the Examiner stated that with respect to claim 21, Mosley also teaches the use of wireless means of transmitting information. See fig. 5a and col. 13, II. 4-47.

Response:

The dependent claims 8, 17 and 19 are dependent upon the amended independent claims 1 and 11 of the present application. The amended independent claims 1 and 11 disclose and claim a self-condensing sensor with a design that promotes in certain environmental conditions, such as when exposed to a patient's breath, to condense as one or more micro-droplet across said antimony sensor and said

reference element (via said reference wick). In additional, the Applicants' device is designed to cooperate with micro-droplets obtained from a certain environmental conditions, such as exposed to a patient's breath, which functions to complete the circuit of the present invention and measure the pH of the micro-droplets.

Neither Christner, Kleinberg nor Mosley disclose or claim a device that includes self-condensing sensor with a design that promotes in certain environment conditions, such as exposure to a patient's breath, to condense as one or more micro-droplets across said antimony sensor and said wick element which is in electrical communication with said reference element. In additional, neither Christner, Kleinberg nor Leonard disclose or claim a device that cooperates with micro-droplets obtained from a patient's breath that function to complete the circuit of the present invention for measuring the pH of the micro-droplets.

In addition, the Applicants argue respectfully that the Examiner has not met the burden of establishing a prima facie case of obviousness in accordance with current patent law.

There are several elements necessary to correctly conclude that a claim of obviousness has been established. One of the primary elements of establishing a prima facie case of obviousness is that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings or the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination."

With respect to this required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." (See *In re Geiger*, 815 F.2d 686, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987). See also *Diversitech Corp. v. Centure Steps, Inc.*, 850 F.2d 675, 678-79, 7 USPQ 2d 1315, 1318 (Fed. Cir. 1988); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 311 (Fed. Cir. 1983):

The Patent Office applies this same standard as explained by the Board, "When the incentive to combine the teachings of the references is not readily apparent, it is the duty of the examiner to explain why combination of the reference teachings is proper....Absent such reasons or incentives, the teachings of the references are not combinable. (*Ex parte Skinner*, 2 USPQ 2d 1788, 1790 (B.P.A.I. 1987)).

Thus, Applicants respectfully submit that claims 8, 17, and 19 are dependent on independent claims 1 and 11 of the present application are patentably distinct and are fully distinguishable over Christner et al. in view of Kleinberg and in further view of Mosley as are independent claims 1 and 11. Withdrawal of this 103(a) rejection is therefore requested.

CLAIM REJECTIONS -35 USC § 103 - CHRISTNER ET AL. (5,346,606) IN VIEW OF KLEINBERG (3,742,594 AND IN FURTHER VIEW OF GLASS ET AL.

The Examiner stated that Christner et al. and Kleinberg reference set forth all the limitations of the claims, but did not explicitly claim a coating on the sensor from the set forth Markush

groupings. The Examiner stated that Glass teaches in an alternate pH sensor that hydrophilic coatings or polyacrylamides facilitate the wetting of the sensor with a sample solution. The Examiner stated that it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Glass for the claimed sensor of Christner and Kleinberg as to ensure the sample sufficiently wets the sensor.

Response:

The dependent claims 25-28 are dependent upon the amended independent claims 1, 11, 22, 23 and 24 of the present application. The amended independent claims 1, 11 22, 23 and 24 disclose and claim a self-condensing sensor with a design that promotes in certain environmental situations, such as exposure to a patient's breath, to condense as one or more micro-droplets across said antimony sensor and said reference element (via said reference wick). In addition, the Applicants' device is designed to cooperate with micro-droplets obtained from a certain environmental situation, such as exposure patient's breath, which functions to complete the circuit of the present invention and measure the pH of the micro-droplets.

Neither Christner, Kleinberg nor Glass et al. disclose or claim a device that includes self-condensing sensor with a design that promotes in certain environment conditions, such as when exposed to a patient's breath, to condense as one or more micro-droplets across said antimony sensor and said wick element which is in electrical communication with said reference element. In addition, neither Christner, Kleinberg nor Glass et al. disclose or claim a device that cooperates with micro-droplets obtained from a patient's breath that function to complete the circuit of the present invention for measuring the pH of the micro-droplets.

In addition, the Applicants argue respectfully that the Examiner has not met the burden of establishing a prima facie case of obviousness in accordance with current patent law.

There are several elements necessary to correctly conclude that a claim of obviousness has been established. One of the primary elements of establishing a prima facie case of obviousness is that the references require some reason, suggestion, or motivation from the prior art as a whole for the person of ordinary skill to have combined or modified the references. With respect to the required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching suggestion or incentive supporting the combination."

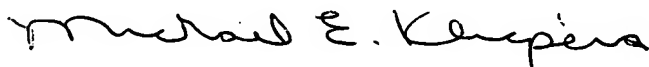
With respect to this required element, the Federal Circuit has stated that "obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination." (See *In re Geiger*, 815 F.2d 686, 2 USPQ 2d 1276, 1278 (Fed. Cir. 1987). See also *Diversitech Corp. v. Centure Steps, Inc.*, 850 F.2d 675, 678-79, 7 USPQ 2d 1315, 1318 (Fed. Cir. 1988); *W.L. Gore & Assocs. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 311 (Fed. Cir. 1983):

The Patent Office applies this same standard as explained by the Board, "When the incentive to combine the teachings of the references is not readily apparent, it is the duty of the examiner to explain why combination of the reference teachings is proper....Absent such reasons or incentives, the teachings of the references are not combinable. (Ex parte Skinner, 2 USPQ 2d 1788, 1790 (B.P.A.I. 1987)).

Thus, Applicants respectfully submit that claims 25-28 that are dependent on independent claims 1, 11, 22, 23 and 24 of the present application are patentably distinct and are fully distinguishable over Christner et al. in view of Kleinberg and in further view of Mosley as are independent claims 1, 11, 22, 23 and 24. Withdrawal of this 103(a) rejection is therefore requested.

Based on the foregoing, Applicant respectfully submits that the application now is in condition for prosecution and allowance. If any matters can be resolved by telephone, the Examiner is invited to call the undersigned attorney at the telephone number listed below.

Respectfully submitted,

A handwritten signature in cursive script, reading "Michael E. Klicpera".

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EXHIBIT A

TERMINAL DISCLAIMER